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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,101	10/19/2001	Robert E. Dudley	-01917590	7711

7590 10/21/2003
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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,101

Applicant(s)

DUDLEY ET AL.

Examiner

Shaojia A Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 12, 2003, June 30, 2003, July 30, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11, 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1, 5-10, 12-13, 15-16, 18, 27, 53, 57-58, 60-64, 80-85, 88, 93, 95, 104, 108-110, 113-118, 120-121, 123-126, 130, 135, 137, and 152

Continuation of Disposition of Claims: Claims rejected are 1, 5-10, 12-13, 15-16, 18, 27, 53, 57-58, 60-64, 80-85, 88, 93, 95, 104, 108-110, 113-118, 120-121, 123-126, 130, 135, 137, and 152

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DETAILED ACTION

Applicant's amendment and response filed May 12, 2003 in Paper No. 7 is acknowledged, wherein claims 6-10, 12-16, 18 and 20 have been amended, and claims 146-151 are newly submitted.

Applicant's Supplemental amendment and response filed on June 30, 2003 has been entered in Paper No. 8 wherein claims 1, 60-61, 64, 104, 115-116, and 119 have been amended, and claims 152-165 are newly submitted.

Applicant's Supplemental amendment and response filed on July 30, 2003 has been entered in Paper No. 10 wherein claims 2-4, 11, 14, 17, 19-21, 54-55, 64, 79, 86-87, 89-92, 94, 96-103, 105-107, 111-112, 119, 122, 127-129, 131-134, 138-151, and 153-165 are cancelled, and claims 1, 5-10, 12-13, 15-16, 18, 27, 53, 57-63, 80-85, 88, 93, 95, 104, 108-110, 113-118, 120-121, 123-126, 130, 135, 137, and 152 have been amended.

Currently, claims 1, 5-10, 12-13, 15-16, 18, 27, 53, 57-58, 60-64, 80-85, 88, 93, 95, 104, 108-110, 113-118, 120-121, 123-126, 130, 135, 137, and 152 are pending in this application.

Applicant's amendment (amending claims 6-21), filed May 12, 2003 in Paper No. 7 with respect to the rejection made under 35 U.S.C. 112 second paragraph for indefinite expressions in these claims of record stated in the Office Action dated January 10, 2003 has been fully considered and is found persuasive to remove the

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rejection since these claims have been amended. Therefore, the said rejection is withdrawn.

Applicant's amendment of the copending Application No. 09/703,753, with respect to the rejection made under obviousness-type double patenting as being unpatentable over 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 of copending Application No. 09/703,753 of record stated in the Office Action dated January 10, 2003 has been fully considered and is found persuasive to remove the rejection since the claims of copending Application No. 09/703,753 have been amended. Therefore, the said rejection is withdrawn.

The following is new rejection(s) necessitated by Applicant's Supplemental amendment filed July 30, 2003 in Paper No. 10 and Applicant's Supplemental amendment filed June 30, 2003 in Paper No. 8.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-10, 12-13, 15-16, 18, 27, 53, 57-58, 60-64, 80-85, 88, 93, 95, 104, 108-110, 113-118, 120-121, 123-126, 130, 135, 137, and 152 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The recitation "subject" in the instant claims renders the claims indefinite. The recitation a "subject" is not clearly defined in the specification. It is unclear as to the meaning of the term "subject" in the claims herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-10, 12-13, 15-16, 18, 27, 53, 57-58, 60-64, 80-85, 88, 93, 95, 104, 108-110, 113-118, 120-121, 123-126, 130, 135, 137, and 152 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-42 of U.S. Patent No. 6,503,894, for the same reasons of record stated in the Office Action dated January 10, 2003.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method for administering a composition to skin of a human subject in need of thereof. The claim of the instant application is drawn to methods of transdermally delivering the same composition to a

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male subject. One having ordinary skill in the art at the time the invention was made would have been motivated to administer the same composition herein a method for administering a composition to skin of a human subject in need of thereof in the patent in to the claimed methods herein of transdermally delivering the same composition to a male subject since these methods between in the patent and in the instant application are seen to substantially overlap.

Thus, the instant claims 1, 5-10, 12-13, 15-16, 18, 27, 53, 57-58, 60-64, 80-85, 88, 93, 95, 104, 108-110, 113-118, 120-121, 123-126, 130, 135, 137, and 152 are seen to be obvious over the claims 18-42 of U.S. Patent No. 6,503,894.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-10, 12-13, 15-16, 18, 27, 53, 57-58, 60-64, 80-85, 88, 93, 95, 104, 108-110, 113-118, 120-121, 123-126, 130, 135, 137, and 152 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

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unpatentable over Claims 43-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all claims pending of the copending Application No. 10/046454.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a method of treating hypogonadism in a male comprising administering the instant composition to a male subject.

The claim of the instant application is drawn to a method of transdermally delivering testosterone to a male subject in need thereof, i.e., a hypogonadal man having primary hypogonadism prior to administration.

One having ordinary skill in the art at the time the invention was made would clearly recognize that these methods between in the copending application and in the instant application are seen to substantially overlap because both have the same method steps, i.e., administering the same composition herein to the same hypogonadal man.

Thus, the instant claims are seen to be anticipated by the claims the all pending claims of copending Application No. 10/046454.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-10, 12-13, 15-16, 18, 27, 53, 57-58, 60-64, 80-85, 88, 93, 95, 104, 108-110, 113-118, 120-121, 123-126, 130, 135, 137, and 152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (WO 99/24041, of record) and Heiber et al. (WO 93/25168, of record), in view of Allen (WO 96/227372, of record).

Mak et al. discloses an enhancement of the penetration of transdermally (percutaneously) or topically applied a pharmaceutical composition comprising an active agent, testosterone, and a penetration-enhancing system that comprises oleic acid (a fatty acid having 17 carbon atoms), C1-C4 alcohol (e.g., ethanol, 2-propanol), and the gelling agent (a thickener), CARBOPOL (a polyacrylic acid). See abstract, page 3 lines 1-5, page 10 Example 1, and Figure 2.

Heiber et al. (WO 93/25168) discloses that testosterone compositions comprising a transdermal (percutaneous) delivery system comprising C2 or C3 alcohol, a penetration enhancer therein, i.e., glycerine, and a gelling agent, are useful in methods moderating and maintaining transdermal drug delivery to the derma at a relatively sustained rate over the duration of application to situs. See abstract, Example 3 at page 19-21, and claims 1-46 and 48.

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The prior art does not expressly disclose the method of Mak or Heiber employing the particular penetration enhancer, isopropyl myristate, and the effective amounts of active ingredients in the composition.

Allen discloses a topical cream composition useful for treating male erectile dysfunction comprising the particular penetration enhancer, isopropyl myristate or glycerine. See abstract and claim 1 and 4.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular penetration enhancer, isopropyl myristate in the method of Mak or Heiber, and optimize the effective amounts of active ingredients in the composition.

One having ordinary skill in the art would have been motivated to employ the particular penetration enhancer, C8-C22 fatty acid and isopropyl myristate in the method for improving the efficacy of the composition herein useful for treating erectile dysfunction in an eugonadal male of the prior art, since the composition containing testosterone of Mak et al. is known to be useful in a method for improving the efficacy of percutaneously delivering a pharmaceutical because this composition further comprises a transdermally or topically penetration-enhancing system encompassing an oleic acid (a fatty acid having 17 carbon atoms), C1-C4 alcohol (e.g., ethanol, 2-propanol), known penetration enhancers and a gelling agent. Moreover, the teachings of Heiber et al. have further provided the motivation to make the present invention since testosterone compositions of Heiber are known to comprise a transdermal (percutaneous) delivery system comprising C2 or C3 alcohol, a penetration enhancer therein, i.e., glycerine, and

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a gelling agent, and these compositions are known to be useful in methods moderating and maintaining transdermal drug delivery to the derma at a relatively sustained rate over the duration of application to skins.

Further, the topical cream composition and method of Allen for treating male erectile dysfunction is known to employ the particular penetration enhancer herein, isopropyl myristate.

Therefore, one of ordinary skill in the art would have found it obvious to employ the particular penetration enhancer herein, isopropyl myristate, in the methods of prior art since isopropyl myristate is another known penetration enhancer in the composition and method of Mak et al. or Heiber for the same usefulness.

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of known effective amounts of known active agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

It is noted that the record contains no clear and convincing evidence of nonobviousness or unexpected results for the combination method herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
October 8, 2003


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

10/25/03